JUN - 5 2007

Premarket Notification [510(k)] Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is : K060434

Company: Horiba ABX
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Date Prepared: 11th April 2007

Device Names:
The following reagents, controls & calibrators are for use in conjunction with the ABX PENTRA 400, cleared to market under K052007.

REAGENTS :

Trade/Proprietary Name:	**ABX PENTRA Albumin CP**
Common or Usual Name:	Albumin
Device Class	Class II
Classification Name:	§862.1035 : Albumin Test System
Product Code:	CIX ; Bromcresol Green Dye-Binding, Albumin

Trade/Proprietary Name:	**ABX PENTRA Micro-albumin CP**
Common or Usual Name:	Micro-albumin
Device Class	Class I
Classification Name:	§866.5040 : Albumin immunological Test System
Product Code:	DCF ; Albumin, Antigen, Antiserum, Control

Trade/Proprietary Name:	**ABX PENTRA Total Protein CP**
Common or Usual Name:	Total Protein
Device Class	Class II
Classification Name:	§862.1635 : Total Protein Test System
Product Code:	CEK ; Biuret (colorimetric), Total Protein

CALIBRATORS:

Trade/Proprietary Name:	**ABX PENTRA µ-Alb Cal**
Common or Usual Name:	µ-Alb Cal
Device Class	Class II
Classification Name:	§862.1150 : Calibrator
Product Code:	JIT ; Calibrator, Secondary

Trade/Proprietary Name:	**ABX PENTRA Multical** (K052007)
Common or Usual Name:	Multical
Device Class	Class II
Classification Name:	§862.1150 : Calibrator
Product Code:	JIX ; Calibrator, Multi-Analyte Mixture

CONTROLS :

Trade/Proprietary Name:	**ABX PENTRA µ-Alb Control L/H**
Common or Usual Name:	µ-Alb Control L/H
Device Class	Class I
Classification Name:	§862.1660 : Quality control material (assayed)
Product Code:	JJX ; Single (Specified) Analyte Controls, assayed

Trade/Proprietary Name:	**ABX PENTRA N Control** (K052007)
Common or Usual Name:	N Control
Device Class	Class I
Classification Name:	§862.1660 : Quality control material (assayed)
Product Code:	JJY ; Multi-Analyte Controls, All Kinds (assayed)

Trade/Proprietary Name:	**ABX PENTRA P Control** (K052007)
Common or Usual Name:	P Control
Device Class	Class I
Classification Name:	§862.1660 : Quality control material (assayed)
Product Code:	JJY ; Multi-Analyte Controls, All Kinds (assayed)

Substantial Equivalence:

The data and information supplied in this submission demonstrates substantial equivalence to their respective predicate devices :

Submission device	Substantially equivalent Predicate device
ABX PENTRA Albumin CP	K896235
ABX PENTRA Micro-albumin CP	K903123
ABX PENTRA Total Protein CP	K896230

Description:

All the reagents, controls and calibrators included in this submission are for use on the **ABX PENTRA 400** (K052007), which is a discrete photometric benchtop clinical chemistry analyzer.

The **ABX PENTRA Albumin CP** is an in vitro diagnostic assay for the quantitative determination of albumin in human serum and plasma based on a colorimetric test using Bromocresol Green (BCG). It is composed of a 99 ml mono-reagent cassette.

The **ABX PENTRA Total Protein CP** is an in vitro diagnostic assay for the quantitative determination of total proteins in human serum and plasma based on a colorimetric test (Biuret reaction). It is composed of a 61 ml mono-reagent cassette.

The **ABX PENTRA Multical** is a lyophilized human serum calibrator with chemical additives and materials of biological origin. The assigned values of the calibrator components are given in the enclosed annex, ensuring optimal calibration of the appropriate HORIBA ABX methods on the ABX PENTRA 400 analyzer.
This calibrator is provided in ten vials of 3 ml.

The **ABX PENTRA N Control** and **ABX PENTRA P Control** are quality control products consisting of lyophilized human serum with chemical additives and materials of biological origin added as required to obtain given component levels. The assigned values of the control components are given in the enclosed annexes, ensuring control of the appropriate HORIBA ABX methods on the ABX PENTRA 400 analyzer. Each control is provided in ten vials of 5 ml.

The **ABX PENTRA Micro-albumin CP** is an in vitro diagnostic assay for the quantitative determination of albumin in human urine based on an immunoturbidimetric test. It is composed of a bi-reagent cassette, with 19 ml and 4.5 ml compartments.

The **ABX PENTRA µ-Alb Cal** is a liquid calibrator prepared by adding purified human albumin to a chemical buffer solution. It has 5 levels to be used for the calibration of the urinary albumin assay. The assigned values are given on the calibrator vials. This calibrator is provided in five vials of 1 ml.

The **ABX PENTRA µ-Alb Control L/H** is a liquid assayed control prepared by adding purified human albumin to a chemical buffer solution. It has 2 levels (Low and High) to be used for the quality control of the urinary albumin assay. The assigned values are given in the enclosed annex. Each level of this calibrator is provided in two vials of 1 ml.

Intended Use :

All reagents in this submission are intended for use on the **ABX PENTRA 400** for the quantitative in-vitro determination of their respective analytes :

- Albumin using human serum and plasma,
- Micro-albumin using urine,
- Total Protein using human serum and plasma.

The controls and calibrators are intended for use in association with the above reagents.

Discussion of Performance Data:

ABX PENTRA Albumin CP :	
Sample type	Serum & plasma
Detection limit	0.02 g/dl
Accuracy and Precision	CV Total < 1.86%
Measuring range	0.46 g/dl – 5.60 g/dl
Upper linearity limit	5.60 g/dl, and with automatic post-dilution : 11.20 g/dl
Correlation (n=272)	Y = 0.94 x + 0.01 with a correlation coefficient r^2 = 0.9864.
Calibration stability	14 days
Reagent stability	closed stability: 36 months at 2-8°C on-board stability (refrigerated area): 83 days

ABX PENTRA Micro-albumin CP :	
Sample type	Urine
Detection limit	4 mg/l
Accuracy and Precision	CV Total < 7.99%
Measuring range	9.0 mg/l – 200 mg/l
Upper linearity limit	200 mg/l, and with automatic post-dilution : 2000 mg/l
Correlation (n=252)	Y = 0.91 x + 3.95 with a correlation coefficient r^2 = 0.9919.
Calibration stability	7 days
Reagent stability	closed stability: 24 months at 2-8°C on-board stability (refrigerated area): 23 days

ABX PENTRA Total Protein CP :	
Sample type	Serum & plasma
Detection limit Quantitation limit	0.14 g/dl 0.60 g/dl
Accuracy and Precision	CV Total < 2.82%
Measuring range	0.60 g/dl – 10 g/dl
Upper linearity limit	10 g/dl, and with automatic post-dilution : 20 g/dl
Correlation	Serum samples (n=230) : Y = 1.03 x + 0.02 with a correlation coefficient r^2 = 0.9841. Plasma samples (n=262) : Y = 0.98 x - 0.02 with a correlation coefficient r^2 = 0.9815.
Calibration stability	1 day
Reagent stability	closed stability: 36 months at 2-8°C on-board stability (refrigerated area): 6 days

CALIBRATORS

ABX PENTRA µ-Alb Cal:	
Analyte	Albumin
Format	Purified human albumin added to a chemical buffer solution
Stability	Closed stability: 12 months at 2°C to 10°C Open stability: 4 weeks at 2°C to 10°C 3 months at -20°C

ABX PENTRA Multical:		
Analytes	Already cleared (K052007, K060205, K060318, K060325, K060854, K062180)	Included in this submission
Alkaline phosphatase	√	√
Alanine aminotransferase	√	√
Amylase	√	√
Aspartate aminotransferase	√	√
Creatine kinase*		
GGT	√	√
Lipase	√	√
Albumin		√
Direct Bilirubin	√	√
Total Bilirubin	√	√
Calcium	√	√
Cholesterol	√	√
Creatinine	√	√
Glucose HK	√	√
Glucose PAP	√	√
Iron	√	√
Lactic acid	√	√
Magnesium	√	√
Phosphorus	√	√
Total Protein		√
Triglycerides	√	√
Urea / Blood Urea Nitrogen	√	√
Uric acid	√	√
Format	Lyophilized human serum with chemical additives and materials of biological origin	
Stability	Closed stability: 24 months at 2-8°C Open stability: Once opened, the calibrator components** are stable for : 8 hours at 15°C to 25°C 2 days at 2°C to 8°C 2 weeks at –25°C to –15°C **Exceptions Direct Bilirubin 3 hours at 15°C to 25°C 8 hours at 2°C to 8°C 2 weeks at –25°C to –15°C Total Bilirubin 6 hours at 15°C to 25°C 1 day at 2°C to 8°C 2 weeks at –25°C to –15°C	

* Not cleared as of date of submission

CONTROLS

ABX PENTRA µ-Alb Control:	
Analyte	Albumin
Format	Purified human albumin added to a chemical buffer solution
Stability	Closed stability: 12 months at 2°C to 10°C Open stability: 4 weeks at 2°C to 10°C

ABX PENTRA N Control:		
Analytes	Already cleared (K052007, K060205, K060318, K060325, K060854, K062180)	Included in this submission
Alkaline phosphatase	√	√
Alanine aminotransferase	√	√
Amylase	√	√
Aspartate aminotransferase	√	√
Creatine kinase*		
GGT	√	√
Lipase	√	√
Albumin		√
Direct Bilirubin	√	√
Total Bilirubin	√	√
Calcium	√	√
Chloride	√	√
Cholesterol	√	√
HDL	√	√
LDL	√	√
Creatinine	√	√
Glucose HK	√	√
Glucose PAP	√	√
Iron	√	√
Lactic acid	√	√
Magnesium	√	√
Phosphorus	√	√
Potassium	√	√
Sodium	√	√
Total Protein		√
Triglycerides	√	√
Urea / Blood Urea Nitrogen	√	√
Uric acid	√	√
		.../...

ABX PENTRA N Control:	
Format	Lyophilized human serum with chemical additives and materials of biological origin
Stability	Closed stability: 30 months at 2-8°C Open stability: Once opened, the control components** are stable for : 12 hours at 15°C to 25°C 5 days at 2°C to 8°C 1 month at –25°C to –15°C **Exceptions Direct Bilirubin 4 hours at 15°C to 25°C 8 hours at 2°C to 8°C 2 weeks at –25°C to –15°C Total Bilirubin 8 hours at 15°C to 25°C 1 day at 2°C to 8°C 2 weeks at –25°C to –15°C

* Not cleared as of date of submission

ABX PENTRA P Control:		
Analytes	Already cleared (K052007, K060205, K060318, K060325, K060854, K062180)	Included in this submission
Alkaline phosphatase	√	√
Alanine aminotransferase	√	√
Amylase	√	√
Aspartate aminotransferase	√	√
Creatine kinase*		
GGT	√	√
Lipase	√	√
Albumin		√
Direct Bilirubin	√	√
Total Bilirubin	√	√
Calcium	√	√
Chloride	√	√
Cholesterol	√	√
HDL	√	√
LDL	√	√
Creatinine	√	√
Glucose HK	√	√
Glucose PAP	√	√
Iron	√	√
Lactic acid	√	√
Magnesium	√	√
Phosphorus	√	√
Potassium	√	√
Sodium	√	√
Total Protein		√
Triglycerides	√	√
Urea / Blood Urea Nitrogen	√	√
Uric acid	√	√
Format	Lyophilized human serum with chemical additives and materials of biological origin	
Stability	Closed stability: 30 months at 2-8°C Open stability: Once opened, the control components** are stable for : 12 hours at 15°C to 25°C 5 days at 2°C to 8°C 1 month at –25°C to –15°C	

	.../... **Exceptions Direct Bilirubin 4 hours at 15°C to 25°C 8 hours at 2°C to 8°C 2 weeks at –25°C to –15°C Total Bilirubin 8 hours at 15°C to 25°C 1 day at 2°C to 8°C 2 weeks at –25°C to –15°C

* Not cleared as of date of submission

Conclusions for Performance Testing :
The performance testing data conclude that the safety and effectiveness of the devices are not compromised, and that they met all acceptance criteria, demonstrating that the devices are substantially equivalent to their respective predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Horiba ABX
c/o Pascal Macziola
Pare Euromedecine Rue Du Caducee
Montpellier, Herault, 34184 France

JUN - 5 2007

Re: k060434

Trade/Device Name: ABX Pentra Albumin CP, ABX Pentra Total Protein CP, ABX Pentra Micro-albumin CP, ABX Pentra – Alb Control L/H, ABX Pentra μ – Alb Cal, ABX Pentra N Control, ABX Pentra P Control, ABX Pentra Multical.
Regulation Number: 21 CFR § 862.1035
Regulation Name: Albumin test system.
Regulatory Class: Class II
Product Code: CIX, CEK, JIQ, JIX, JIT, JJY
Dated: April 13, 2007
Received: April 16, 2007

Dear Pascal Macziola:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060434

Device Name: Proteins on ABX PENTRA 400 Clinical Chemistry Analyzer

Indications For Use:

Proteins reagents, with associated calibrators and controls, are intended for use on ABX PENTRA 400 Clinical Chemistry Analyzer to measure a variety of analytes.

ABX PENTRA Albumin CP reagent, with associated calibrators and controls, is a diagnostic reagent for quantitative determination of Albumin in serum and plasma by colorimetry.
Albumin measurements are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

K060434

Indications for Use

510(k) Number (if known): K060434

Device Name: Proteins on ABX PENTRA 400 Clinical Chemistry Analyzer

Indications For Use:

ABX PENTRA Total Protein CP reagent, with associated calibrators and controls, is a diagnostic reagent for quantitative in-vitro determination of Total Proteins in serum and plasma by colorimetry.
Measurements obtained by this device are used in the diagnosis and treatment of a variety of diseases involving the liver, kidney, or bone marrow as well as other metabolic or nutritional disorders.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K060434

Indications for Use

510(k) Number (if known): K060434

Device Name: Proteins on ABX PENTRA 400 Clinical Chemistry Analyzer

Indications For Use:

ABX PENTRA Micro-albumin CP reagent, with associated calibrators and controls, is a diagnostic reagent for quantitative in-vitro determination of Albumin in urine (µALB) at low concentration by immunoturbidimetric assay.
Measurements of albumin aids in the diagnosis of diabetic nephritis and other kidney and intestinal diseases.

The ABX PENTRA µ-Alb Cal is a calibrator for use in the calibration of quantitative Horiba ABX PENTRA Micro-albumin CP method on Horiba ABX clinical chemistry analyzers.

The ABX PENTRA µ-Alb Control L/H is for use in quality control by monitoring accuracy and precision for the quantitative ABX PENTRA Micro-albumin CP method.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Office of In Vitro Diagnostic Device
Evaluation and Safety

K060434

Indications for Use

510(k) Number (if known): K060434

Device Name: ABX PENTRA Multical

Indications For Use:

The ABX PENTRA Multical is a calibrator for use in the calibration of quantitative Horiba ABX methods on Horiba ABX clinical chemistry analyzers.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Indications for Use

510(k) Number (if known): K060434

Device Name: ABX PENTRA N Control

Indications For Use:

The ABX PENTRA N Control is for use in quality control by monitoring accuracy and precision.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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K060434

Indications for Use

510(k) Number (if known): K060434

Device Name: ABX PENTRA P Control

Indications For Use:

The ABX PENTRA P Control is for use in quality control by monitoring accuracy and precision.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Office of In Vitro Diagnostic Device Evaluation and Safety

K060434

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